

Remarks:

Applicants have cancelled claims 4, 8-9, 20-21, 29-30, 34, and 38, without prejudice. Applicants expressly reserve the right to pursue the cancelled subject matter in one or more subsequent applications that claim priority under 35 U.S.C. § 120 from this application.

Applicants have amended claims 1, 10, 25, and 31 to more particularly point out and distinctly claim the subject matter that they wish to prosecute in this application. Support for these claims is found throughout the application for exemplary locations: Examples 15 and 16, pages 39-31 and Figure 12.

None of these amendments adds new matter. Upon entry of the amendments, claims 1-3, 5-7, 10-19, 22-28, 31-33, 35-37 and 40-48 will be pending. Of those claims, claims 10-19 and 22-24 are pending but withdrawn as being directed to a non-elected invention. Applicants request entry of the amendments and reconsideration of the pending claims.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-9, 25-38, 40, 42, 43, 45, 46 and 48 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over US2003/0138417 A1 ("the '417 publication") as is evidenced by the SYNAGIS® product information sheet in view of U.S. Pat. No. 5,580,856 ("the '856 patent"). The Examiner asserts that the '417 publication "teaches" a stable liquid formulation comprising 50 mg/ml IgG2 such as HuEP5C7, human monoclonal antibody to selectin in 50 mM histidine, arginine and 125 mM NaCl in the presence of polysorbate, and that many antibodies in the market are supplied with sterile water for injection such as Synagis. The Examiner concedes that the '417 publication does not teach solid formulations such as a lyophilized formulation or use of arginine in a concentration of 15 mM-60 mM. The Examiner alleges that the '856 patent "teaches" that a process of drying is often employed to stabilize proteins in a lyophilized formulation for long-term storage in broader temperature ranges, and

the use of arginine in concentrations of about 0.5-5%, which is equivalent to 28.9 mM. In view of the claim amendments, applicants traverse.

Solely in an effort to expedite prosecution, applicants have amended claims 1, 25 and 31 to specify that the concentration of histidine is about 15 mM and the concentration of arginine is about 15 mM. Support for the amendment is found throughout the specification (e.g. at Examples 15 and 16, pages 39-31 and Figure 12).

None of the cited documents teach or suggest this specific combination of histidine and arginine at about 15 mM. For at least that reason, the cited documents taken alone or together cannot render the instant claims obvious. Accordingly, the rejections should be withdrawn.

Claims 1, 41, 44, and 47 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over US2003/0138417 and U.S. Pat. No. 5,580,856 in view of U.S. Pat. No. 4,849,352 ("the '352 patent"). The Examiner acknowledges that the '417 publication and the '856 patent do not teach immunospecific antibody fragments. The Examiner states that the '352 patent "teaches a pharmaceutical composition comprising a polyclonal F(ab')₂ that binds to any antigen, pepsin digested followed by ammonium sulfate precipitation". In view of the claim amendments, applicants traverse.

Claims 1, 41, 44, and 47 are not rendered obvious for the reasons claim 1 is not obvious above regardless of what the '352 patent may say about antibody fragments. The '352 patent does not remedy the deficiencies of the other cited documents. None of the cited documents, thus, alone, or in any combination renders obvious the subject matter of claims 1, 41, 44, and 47. The rejection of claims 1, 41, 44, and 47 should be withdrawn.

Claim Rejections under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 1-7, 25-28, 31-38, and 40-48 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner argues that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner alleges that the specification does not provide support for a concentration of histidine being 5-30 mM or less than 30 mM. In view of the claim amendments, applicants traverse.

Support for the claims may be found in the specification as it would be read and understood by one of ordinary skill in the art. The instant specification clearly states that any amount of histidine, sufficient to stabilize at least one antibody, can be used with solid and liquid formulations (see for example, page 3, paragraph 11-13; page 4, paragraph 18; and page 9, paragraph 41). Paragraph 41 shows a non-exhaustive list of concentrations of histidine of about 6 mM through 60 mM and regular intervals in between.

Solely in an effort to expedite prosecution, applicants have amended claims 1, 25 and 31 to specify that the concentration of histidine is about 15 mM and the concentration of arginine is about 15 mM. Support for the amendment is found throughout the specification (e.g. at Examples 15 and 16, pages 39-31 and Figure 12). Reconsideration and withdrawal of this rejection are respectfully requested.

Rejections Under 35 U.S.C. § 102

Claims 1-9, 25-38, and 40-48 are rejected under 35 U.S.C. § 102(a) or (e), as allegedly anticipated by US2002/0045571 A2 ("the '571 publication"). The Examiner asserts that the '571 publication "teaches" that the stable antibody formulation at about 80 mg/ml containing about 50-100 mM histidine and arginine (claims 45-50, in particular) in presence of sugars, trehalose or polysorbate (claims 59-60, in particular) and this antibody formulation can be lyophilized ([0133-136], in particular). In view of the claim amendments, applicants traverse.

Nonetheless, solely to expedite prosecution, applicants have amended claims 1, 25 and 31 to specify that the concentration of histidine is about 15 mM and the concentration of arginine is about 15 mM. Support for the amendment is found throughout the specification (e.g. at Examples 15 and 16, pages 39-31 and Figure 12).

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In sum, the '571 publication does not disclose all the limitations of the present claims, as amended, and thus fails to anticipate the claimed subject matter. Reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(a) or (e) are respectfully requested.

In view of the foregoing, applicants request withdrawal of the rejections and allowance of the claims.

Applicant believes no fee is due other than the fee for the two month extension of time is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-1075, under Order No. ABGENIX.058A (ABX-HIS) from which the undersigned is authorized to draw.

Respectfully submitted,



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